EXHIBIT E

QUALITY ASSURANCE/QUALITY CONTROL PROCEDURES AND REQUIREMENTS

Exhibit E - Quality Assurance/Quality Control Procedures and Requirements
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1.0 OVERVIEW

1.1 Quality assurance and quality control are integral parts of the Environmental Protection Agency's (EPA) Regional Environmental Analytical Procurement (REAP) program. The quality assurance (QA) process consists of management review and oversight at the planning, implementation, and completion stages of the environmental data collection activity, and ensures that data provided are of the quality required. The quality control (QC) process includes those activities required during data collection to produce the data quality desired and to document the quality of the collected data.

1.2 During the planning of an environmental data collection program, QA activities focus on defining data quality criteria and designing a QC system to measure the quality of data being generated. During the implementation of the data collection effort, QA activities ensure that the QC system is functioning effectively, and that the deficiencies uncovered by the QC system are corrected. After environmental data are collected, QA activities focus on assessing the quality of data obtained to determine its suitability to support enforcement or remedial decisions.

1.3 This exhibit describes the overall QA/QC operations and the processes by which the REAP program meets the objectives defined above. This contract requires a variety of QA/QC activities. These contract requirements are the minimum QC operations necessary to satisfy the analytical requirements associated with the determination of the different method analytes. These QC operations are designed to facilitate laboratory comparison by providing EPA with comparable data from all Contractors. These requirements do not release the analytical Contractor from maintaining their own QC checks on method and instrument performance.

2.0 INTRODUCTION

2.1 Appropriate use of data generated under the large range of analytical conditions encountered in environmental analyses requires reliance on the QC procedures and criteria incorporated into the methods. Several of the methods in this contract have been validated on samples typical of those received by the laboratories in the Contract Laboratory Program (CLP). However, the validation of these methods does not guarantee that they perform equally well for all sample matrices encountered. Inaccuracies can also result from causes other than unanticipated matrix effects, such as sampling artifacts, equipment malfunctions, and operator error. Therefore, the quality control component of each method is indispensable.

2.2 The data acquired from QC procedures are used to estimate and evaluate the information content of analytical results and to determine the necessity for or the effect of corrective action procedures. The parameters used to estimate information content include precision, accuracy, detection limit, and other quantitative and qualitative indicators. In addition, QC procedures give an overview of the activities required in an integrated program to generate data of known and documented quality required to meet defined objectives.

2.3 The necessary components of a complete QA/QC program include internal QC criteria that demonstrate acceptable levels of performance, as determined by QA review. External review of data and procedures is accomplished by the monitoring activities of the EPA. Each external review accomplishes a different purpose. These reviews are described in specific sections of this Exhibit. Laboratory evaluation samples, GC/MS and/or GC tape audits, and data packages provide an external QA reference for the program. An on-site evaluation is also part of the external QA monitoring system. A feedback loop provides the results of the various review functions to the Contractors through direct communications with the EPA.

2.4 This exhibit does not provide specific instructions for constructing QA plans, QC systems, or a QA organization. It is, however, an explanation of the QA/QC requirements of the program. It outlines some minimum standards for QA/QC programs. It also includes specific items that are required in a QA plan and by the QA/QC documentation detailed in this contract. Delivery of this documentation provides the Agency with a complete data package which will stand alone, and limits the need for contact with the Contractor or with an analyst, at a later date, if some aspect of the analysis is questioned.

2.5 In order to assure that the product delivered by the Contractor meets the requirements of the contract, and to improve interlaboratory data comparison, the Agency requires the following from the Contractor:

- Preparation of and adherence to a written laboratory quality assurance plan, the elements of which are designated in Section 3,
- Preparation of and adherence to QA/QC standard operating procedures as described in Section 4,
- Adherence to the analytical methods and associated QC requirements specified in the contract,
- Verification of analytical standards and documentation of the purity of neat materials and the purity and accuracy of solutions obtained from private chemical supply houses,
- Submission of all raw data and pertinent documentation for Regional review,
- Participation in the analysis of laboratory evaluation samples, including adherence to corrective action procedures,
- Submission, upon request, of GC/MS tapes and applicable documentation for tape audits, including a copy of the sample data package,

- Submission, upon request, of GC tapes and applicable documentation for tape audits, including a copy of the sample data package,
- Participation in on-site laboratory evaluations, including adherence to corrective action procedures, and
- Submission of all original documentation generated during sample analyses for Agency review.

2.6 In order for the QA/QC information to reflect the status of the samples analyzed, all samples and their QA/QC analysis shall be analyzed under the same operating and procedural conditions.

2.7 If any QC measurement fails to meet contract criteria, the analytical measurement may not be repeated prior to taking the appropriate corrective action as specified in Exhibit D.

2.8 The Contractor shall report all QC data in the exact format specified in Exhibit B.

2.9 Sensitivity, method detection limits, precision, linear range shall be established for each compound on a particular instrument. All reported measurements shall be within the instrument linear range. The analyst shall maintain quality control data confirming instrument performance and analytical results.

2.10 The Contractor shall establish a quality assurance program with the objective of providing sound analytical chemical measurements. This program shall incorporate the quality control procedures, any necessary corrective action, and all documentation required during data collection as well as the quality assessment measures performed by management to ensure acceptable data production.

3.0 LABORATORY QUALITY ASSURANCE PLAN

3.1 Introduction. The Contractor shall establish a laboratory quality assurance program with the objective of providing sound analytical chemical measurements. This program shall incorporate the quality control procedures, any necessary corrective action, and all documentation required during data collection as well as the quality assessment measures performed by management to ensure acceptable data production.

3.1.1 As evidence of such a program, the Contractor shall prepare a written laboratory quality assurance plan (LQAP) which describes the procedures that are implemented to achieve the following:

- Maintain data **integrity**, **validity**, and **usability**,
- Ensure that analytical measurement systems are maintained in an acceptable state of stability and reproducibility,
- Detect problems through data assessment and establish corrective action procedures which keep the analytical process reliable, and
- Document all aspects of the measurement process in order to provide data which are technically sound and legally defensible.

3.1.2 The LQAP shall present, in specific terms, the policies, organization, objectives, functional guidelines, and specific QA and QC activities designed to achieve the data quality requirements in this contract. Where applicable, standard operating procedures pertaining to each element shall be included or referenced as part of the LQAP. The LQAP shall be paginated consecutively in ascending order. The LQAP shall be available during on-site laboratory evaluations. Additional information relevant to the preparation of a LQAP can be found in Agency and American Society for Testing and Materials publications.

3.2 Required Elements of a Laboratory Quality Assurance Plan. The required elements of a laboratory's LQAP are outlined in this section. This outline should be used as a framework for developing the LQAP.

A. Organization and Personnel

1. QA Policy and Objectives
2. QA Management
    a. Organization
    b. Assignment of QC and QA Responsibilities
    c. Reporting Relationships
    d. QA Document Control Procedures
    e. QA Program Assessment Procedures
3. Personnel
    a. Resumes
    b. Education and Experience
    c. Training Progress

B. Facilities and Equipment

1. Instrumentation and Backup Alternatives
2. Maintenance Activities and Schedules

C. Document Control

1. Contractor Notebook Policy
2. Sample Tracking/Custody Procedures
3. Logbook Maintenance and Archiving Procedures
4. Case File Organization, Preparation and Review Procedures
5. Procedures for Preparation, Approval, Review, Revision, and Distribution of Standard Operating Procedures
6. Process for Revision of Technical or Documentation Procedures

D. Analytical Methodology

1. Calibration Procedures and Frequency
2. Sample Preparation/Extraction Procedures
3. Sample Analysis Procedures
4. Standards Preparation Procedures
5. Decision Processes, Procedures, and Responsibility for Initiation of Corrective Action

E. Data Generation

1. Data Collection Procedures
2. Data Reduction Procedures
3. Data Validation Procedures
4. Data Reporting and Authorization Procedures

F. Quality Control

1. Solvent, Reagent and Adsorbent Check Analysis
2. Reference Material Analysis
3. Internal Quality Control Checks
4. Corrective Action and Determination of QC Limit Procedures
5. Responsibility Designation

G. Quality Assurance

1. Data Quality Assurance
2. Systems/Internal Audits
3. Performance/External Audits
4. Corrective Action Procedures
5. Quality Assurance Reporting Procedures
6. Responsibility Designation

H. Safety Programs - Training and Documentation

I. Compliance with Environmental Regulations

1. Air Pollution Prevention Measures
2. Aqueous Effluent Discharge
3. Hazardous and Nonhazardous Waste Management Practices
4. Hazardous Waste Manifesting

3.3 Updating and Submitting the Laboratory Quality Assurance Plan

3.3.1 Initial Submission. During the contract solicitation process, the Contractor is required to submit their LQAP to the EPA. Within twenty eight (28) days after contract award, the Contractor shall submit their LQAP which is in compliance with the requirements of this contract to EPA. Within 42 days of receipt of the LQAP, EPA will either provide written comments to the Contractor or approve the LQAP. Within 14 days of receipt of EPA written comments, the Contractor shall submit a revised LQAP which is in compliance with the requirements of this contract. The Contractor shall maintain on file a revised LQAP, fully compliant with the requirements of this contract. The revised LQAP will become the official LQAP under the contract and may be used during legal proceedings. The Contractor shall maintain the LQAP on file at the Contractor's facility for the term of the contract. Both the initial submission and the revised LQAP shall be paginated consecutively in ascending order. The revised LQAP shall include:

- Changes resulting from (1) the Contractor's internal review of their organization, personnel, facility, equipment, policy and procedures and (2) the Contractor's implementation of the requirements of the contract, and
- Changes resulting from the Agency's review of the laboratory evaluation sample data, bidder-supplied documentation, and recommendations made during the pre-award on-site laboratory evaluation.

3.3.1.1 The Contractor shall send a copy of the current LQAP within 7 days of a request from the EPA. The Agency requestor will designate the recipients.

3.3.2 Subsequent Updates and Submissions. During the term of the contract, the Contractor shall amend the LQAP when the following circumstances occur:

- The Agency modifies the contract,
- The Agency notifies the Contractor of deficiencies in the LQAP,
- The Agency notifies the Contractor of deficiencies resulting from the Agency's review of the Contractor's performance,
- The Contractor identifies deficiencies resulting from the internal review of the LQAP,
- The Contractor's organization, personnel, facility, equipment, policy or procedures change, or
- The Contractor identifies deficiencies resulting from the internal review of changes in their organization, personnel, facility, equipment, policy or procedures.

3.3.2.1 The Contractor shall amend the LQAP within 28 days of when the circumstances listed above result in a discrepancy between what was previously described in the LQAP and what is presently occurring at the Contractor's facility. When the LQAP is amended, all changes in the LQAP shall be clearly marked (e.g., a bar in the margin indicating where the change is found in the document, or highlighting the change by underlining the change, bold printing the change, or using a different print font). The amended pages shall have the date on which the changes were implemented. The Contractor shall incorporate all amendments to

the current LQAP. The Contractor shall archive all amendments to the LQAP for future reference by the Agency.

3.3.2.2 The Contractor shall send a copy of the current LQAP within 7 days of a request from the EPA. The Agency requestor will designate the recipients.

3.4 Corrective Actions. If the Contractor fails to adhere to the requirements listed in Section 3, the Contractor may expect, but the Agency is not limited to, the following actions: reduction of numbers of samples sent under this contract, suspension of sample shipment to the Contractor, a GC/MS or GC tape audit, a data package audit, an on-site laboratory evaluation, a remedial laboratory evaluation sample, and/or contract sanctions, such as a Cure Notice.

4.0 STANDARD OPERATING PROCEDURES

4.1 Introduction. In order to obtain reliable results, adherence to prescribed analytical methodology is imperative. In any operation that is performed on a repetitive basis, reproducibility is best accomplished through the use of standard operating procedures (SOPs). As defined by EPA, an SOP is a written document which provides directions for the step-by-step execution of an operation, analysis, or action which is commonly accepted as the method for performing certain routine or repetitive tasks.

4.1.1 SOPs prepared by the Contractor shall be functional (i.e., clear, comprehensive, up-to-date, and sufficiently detailed to permit duplication of results by qualified analysts). The SOPs shall be paginated consecutively in ascending order.

4.1.2 All SOPs shall reflect activities as they are currently performed by the Contractor. In addition, all SOPs shall be:

- Consistent with current Agency regulations, guidelines, and the REAP contract's requirements.
- Consistent with instrument manufacturers' specific instruction manuals.
- Available to the Agency during an on-site laboratory evaluation. A complete set of SOPs shall be bound together and available for inspection at such evaluations. During on-site evaluations, Contractor personnel may be asked to demonstrate the application of the SOPs.
- Available to the designated recipients within 7 days, upon request by the EPA.
- Capable of providing for the development of documentation that is sufficiently complete to record the performance of all tasks required by the protocol.
- Capable of demonstrating the validity of data reported by the Contractor and explaining the cause of missing or inconsistent results.
- Capable of describing the corrective measures and feedback mechanism utilized when analytical results do not meet protocol requirements.
- Reviewed regularly and updated as necessary when contract, facility, or Contractor procedural modifications are made.
- Archived for future reference in usability or evidentiary situations.
- Available at specific work stations as appropriate.
- Subject to a document control procedure which precludes the use of outdated or inappropriate SOPs.

4.2 Format. The format for SOPs may vary depending upon the kind of activity for which they are prepared; however, at a minimum, the following sections shall be included:

- Title page,
- Scope and application,
- Definitions,
- Procedures,
- QC limits,
- Corrective action procedures, including procedures for secondary review of information being generated,

- Documentation description and example forms,
- Miscellaneous notes and precautions, and
- References.

4.3 Requirements. The Contractor shall maintain the following SOPs.

4.3.1 Evidentiary SOPs for required chain-of-custody and document control are discussed in Exhibit F.

4.3.2 Sample Receipt and Storage

- Sample receipt and identification logbooks
- Refrigerator temperature logbooks
- Extract storage logbooks
- Security precautions

4.3.3 Sample Preparation

- Reagent purity check procedures and documentation
- Extraction procedures
- Extraction bench sheets
- Extraction logbook maintenance

4.3.4 Glassware Cleaning

4.3.5 Calibration (Balances)

- Procedures
- Frequency requirements
- Preventative maintenance schedule and procedures
- Acceptance criteria and corrective actions
- Logbook maintenance

4.3.6 Analytical Procedures (for each Analytical System, including GPC)

- Instrument performance specifications
- Instrumental operating procedures
- Data acquisition system operation
- Procedures when automatic quantitation algorithms are overridden
- QC required parameters
- Analytical run/injection logbooks
- Instrumental error and editing flag descriptions and resulting corrective actions

4.3.7 Maintenance Activities (for each Analytical System, including GPC)

- Preventative maintenance schedule and procedures
- Corrective maintenance determinants and procedures
- Maintenance authorization

4.3.8 Analytical Standards

- Standard coding/identification and inventory system

- Standards preparation logbook(s)
- Standards preparation procedures
- Procedures for equivalency/traceability analyses and documentation
- Purity logbook (primary standards and solvents)
- Storage, replacement, and labelling requirements
- QC and corrective action measures

4.3.9 Data Reduction Procedures

- Data processing systems operation
- Outlier identification methods
- Identification of data requiring corrective action
- Procedures for format and/or forms for each operation

4.3.10 Documentation Policy/Procedures

- Contractor/analysts' notebook policy, including review policy
- Complete SDG File contents
- Complete SDG File organization and assembly procedures, including review policy
- Document inventory procedures, including review policy

4.3.11 Data Validation/Self-Inspection Procedures

- Data flow and chain-of-command for data review
- Procedures for measuring precision and accuracy
- Evaluation parameters for identifying systematic errors
- Procedures to ensure that hardcopy is complete and compliant with the requirements in Exhibits B.
- Demonstration of internal QA inspection procedure (demonstrated by supervisory sign-off on personal notebooks, internal performance evaluation samples, etc.)
- Frequency and type of internal audits (e.g., random, quarterly, spot checks, perceived trouble areas)
- Demonstration of problem identification, corrective actions and resumption of analytical processing; sequence resulting from internal audit (i.e., QA feedback)
- Documentation of audit reports (internal and external), audit response, corrective action, etc.

4.3.12 Data Management and Handling

- Procedures for controlling and estimating data entry errors
- Procedures for reviewing changes to data and deliverables and ensuring traceability of updates
- Life cycle management procedures for testing, modifying and implementing changes to existing computing systems including hardware, software, and documentation or installing new systems
- Database security, backup and archival procedures including recovery from system failures

- System maintenance procedures and response time
- Individuals(s) responsible for system operation, maintenance, data integrity and security
- Specifications for staff training procedures
- Storage, retrieval and verification of the completeness and readability of GC/MS and GC files transferred to magnetic media

4.4 Submitting and Updating SOPs

4.4.1 Initial Submission. During the contract solicitation process, the Contractor is required to submit their SOPs to the EPA. Within twenty eight (28) days after contract award, the Contractor shall submit a complete set of SOPs which is in compliance with the requirements of this contract to EPA. Within 42 days of receipt of the SOPs, EPA will either provide written comments to the Contractor or approve the SOPs. Within 14 days of receipt of EPA written comments, the Contractor shall submit a complete revised set of SOPs which are in compliance with the requirements of this contract. The Contractor shall maintain on file a complete revised set of SOPs, fully compliant with the requirements of this contract. The revised SOPs will become the official SOPs under the contract and may be used during legal proceedings. The Contractor shall maintain the complete set of SOPs on file at the Contractor's facility for the term of the contract. Both initial submission of SOPs and the revised SOPs shall be paginated consecutively in ascending order. The revised SOPs shall include:

- Changes resulting from (1) the Contractor's internal review of their procedures and (2) the Contractor's implementation of the requirements of the contract, and
- Changes resulting from the Agency's review of the laboratory evaluation sample data, bidder-supplied documentation, and recommendations made during the pre-award on-site laboratory evaluation.

4.4.1.1 The Contractor shall send a complete set of current SOPs or individually requested SOPs within 7 days of a request from the EPA. The Agency requestor will designate the recipients.

4.4.2 Subsequent Updates and Submissions. During the term of the contract, the Contractor shall amend the SOPs when the following circumstances occur:

- The Agency modifies the contract,
- The Agency notifies the Contractor of deficiencies in their SOPs,
- The Agency notifies the Contractor of deficiencies resulting from the Agency's review of the Contractor's performance,
- The Contractor's procedures change,
- The Contractor identifies deficiencies resulting from the internal review of their SOPs documentation, or
- The Contractor identifies deficiencies resulting from the internal review of their procedures.

4.4.2.1 Existing SOPs shall be amended or new SOPs shall be written within 28 days of when the circumstances listed above result in a discrepancy between what was previously described in the SOPs and what is presently occurring at the Contractor's facility. All changes in the SOPs shall be clearly marked (e.g., a bar in the margin indicating where the change is in the document, or highlighting the change by underlining the change, bold printing the change, or using a different print font). The amended/new SOPs shall have the date on which the changes were implemented.

4.4.2.2 When existing SOPs are amended or new SOPs are written, the Contractor shall document the reason(s) for the change, and maintain the amended or new SOPs on file at the laboratory facility. Documentation of the reason(s) for the changes shall be maintained on file with the amended SOPs or new SOPs.

4.4.2.3 The Contractor shall send a complete set of current SOPs or individually requested SOPs within 7 days of a request from the EPA. The Agency requestor will designate the recipients.

4.4.2.4 Documentation of the reason(s) for changes to the SOPs shall also be submitted with the SOPs. An alternate delivery schedule for submitting the amended/new SOPs and their documentation may be proposed by the Contractor, but it is the sole decision of the Agency to approve or disapprove the alternate delivery schedule. If an alternate delivery schedule is proposed, the Contractor shall describe in a letter to the EPA why he/she is unable to meet the delivery schedule listed in this section. The EPA will not grant an extension for greater than 28 days for amending/writing new SOPs. The EPA will not grant an extension for greater than 14 days for submission of the letter documenting the reasons for the changes and for submitting amended/new SOPs. The Contractor shall proceed and not assume that an extension will be granted until so notified by the EPA.

4.5 Corrective Actions. If the Contractor fails to adhere to the requirements listed in Section 4, the Contractor may expect, but the Agency is not limited to, the following action: reduction of number of samples sent under this contract, suspension of sample shipment to the Contractor, a GC/MS or GC tape audit, a data package audit, an on-site laboratory evaluation, a remedial laboratory evaluation sample, and/or contract sanctions, such as a Cure Notice.

5.0 ANALYTICAL STANDARDS REQUIREMENTS

5.1 Overview. EPA will not supply analytical reference standards either for direct analytical measurements or for the purpose of traceability. All Contractors shall be required to prepare from neat materials or purchase from private chemical supply houses those standards necessary to successfully and accurately perform the analyses required in this protocol.

5.2 Preparation of Chemical Standards from the Neat High Purity Bulk Material. A Contractor may prepare their chemical standards from neat materials. Contractors shall obtain the highest purity possible when purchasing neat chemical standards; when standards are purchased at less than 97% purity, the Contractor shall document the reason why a higher purity could not be obtained.

5.2.1 Neat chemical standards shall be kept refrigerated when not being used in the preparation of standard solutions. Proper storage of neat chemicals is essential in order to safeguard them from decomposition.

5.2.2 The purity of a compound can sometimes be misrepresented by a chemical supply house. Since knowledge of purity is needed to calculate the concentration of solute in a solution standard, it is the Contractor's responsibility to have analytical documentation ascertaining that the purity of each compound is correctly stated. Purity confirmation, when performed, should use either differential scanning calorimetry, gas chromatography with flame ionization detection, high performance liquid chromatography, infrared spectrometry, or other appropriate techniques. Use of two or more independent methods is recommended. The correction factor for impurity when weighing neat materials in the preparation of solution standards is:

EQ. 1

$$weight\ of\ impure\ compound = \frac{weight\ of\ pure\ compound}{(percent\ purity/100)}$$

where "weight of pure compound" is that required to prepare a specific volume of a standard solution at a specified concentration.

5.2.3 When compound purity is assayed to be 97% or greater, the weight may be used without correction to calculate the concentration of the stock standard. If the compound purity is assayed to be less than 97%, the weight shall be corrected when calculating the concentration of the stock solution.

5.2.4 Mis-identification of compounds occasionally occurs and it is possible that a mislabeled compound may be received from a chemical supply house. It is the Contractor's responsibility to have analytical documentation ascertaining that all compounds used in the preparation of solution standards are correctly identified. Identification confirmation, when performed, shall use gas chromatography/mass spectrometry analysis on at least two different analytical columns, or other appropriate techniques.

5.2.5 Calculate the weight of material to be weighed out for a specified volume taking into account the purity of the compound and the desired concentration. A second person shall verify the accuracy of the calculations. Check balances for accuracy with a set of standard weights every 12 hours. All weighing shall be performed on an analytical balance to the nearest 0.1 mg and verified by a second person. The solvent used to dissolve the solute shall be compatible with the protocol in which the standard is to be used; the solute shall be soluble, stable, and nonreactive with the solvent. In the case of a multicomponent solution, the components must not react with each other.

5.2.6 Transfer the solute to a volumetric flask and dilute to the specified solution volume with solvent after ensuring dissolution of the solute in the solvent. Sonication or warming may be performed to promote dissolution of the solute. This solution shall be called the primary standard and all subsequent dilutions shall be traceable back to the primary standard.

5.2.7 Log notebooks shall be kept for all weighing and dilutions. All subsequent dilutions from the primary standard and the calculations for determining their concentrations shall be recorded and verified by a second person. All solution standards shall be refrigerated when not in use. All solution standards shall be clearly labeled as to the identity of the compound or compounds, concentration, date prepared, solvent, and initials of the preparer.

5.3 Purchase of Chemical Standards Already in Solution. Solutions of analytical reference standards can be purchased by Contractors provided they meet the following criteria.

5.3.1 Contractors shall maintain the following documentation to verify the integrity of the standard solutions they purchase:

- Mass spectral identification confirmation of the solution,
- Purity confirmation of the solution, and
- Chromatographic and quantitative documentation that the solution standard was QC checked according to the following section.

5.3.2 The Contractor shall purchase standards for which the quality is demonstrated statistically and analytically. One way this may be demonstrated is to prepare and analyze three solutions, a high standard, a low standard, and a standard at the target concentration (see Sections 5.3.2.1 and 5.3.2.2). The Contractor shall have documentation to demonstrate that the analytical results for the high standard and low standard are consistent with the difference in theoretical concentrations. This is done by the Student's t-test in Section 5.3.2.4. If this is achieved, the Contractor shall then demonstrate that the concentration of the target standard lies midway between the concentrations of the low and high standards. This is done by the Student's t-test in Section 5.3.2.5. The standard is certified to be within 10% of the target concentration using the equations in Section 5.3.2.6. If this procedure is used, the Contractor shall document that the following have been achieved.

5.3.2.1 Two solutions of identical concentration shall be prepared independently from solutions. An aliquot of the first solution shall be diluted to the intended concentration (the "target standard"). One aliquot is taken from the second solution and diluted to a concentration 10% greater than the target standard. This is called the "high standard." One further aliquot is taken from the second solution and diluted to a concentration 10% less that the target standard. This is called the "low standard."

5.3.2.2 Six replicate analyses of each standard (a total of 18 analyses) shall be performed in the following sequence: low standard, target, high standard, low standard, target standard, high standard, ...

5.3.2.3 The mean and variance of the six results for each solution shall be calculated.

EQ. 2

$$Mean = \frac{\sum_{i=1}^{6} Y_i}{6}$$

EQ. 3

$$Variance = \frac{\sum_{i=0}^{6} Y_i^2 - 6(MEAN)^2}{5}$$

The values Y_i represent the results of the six analyses of each standard. The means of the low, target, and high standards are designated M_1, M_2, and M_3, respectively. The variances of the low, target, and high standards are designated V_1, V_2, and V_3, respectively. Additionally, a pooled variance, V_p, is calculated.

EQ. 4

$$V_p = \frac{\frac{V_1}{0.81} + V_2 + \frac{V_3}{1.21}}{3}$$

If the square root of V_p is less than 1% of M_2, then $M_2^2/10{,}000$ shall be used as the value of V_p in all subsequent calculations.

5.3.2.4 The test statistic shall be calculated.

EQ. 5

$$Test\ Statistic = \frac{\left| \frac{M_3}{1.1} - \frac{M_1}{0.9} \right|}{\sqrt{\frac{V_p}{3}}}$$

If the test statistic exceeds 2.13 then a 20% difference between the high and low standards exists. In such a case, the standards are not acceptable.

5.3.2.5 The test statistic shall be calculated.

EQ. 6

$$Test\ Statistic = \frac{\left| M_2 - \frac{M_1}{1.8} - \frac{M_3}{2.2} \right|}{\sqrt{\frac{V_p}{4}}}$$

If the test statistic exceeds 2.13, then the target standard concentration has not been demonstrated to be the midway between the high and low standards. In such a case, the standards are not acceptable.

5.3.2.6 The 95% confidence intervals for the mean result of each standard shall be calculated.

EQ. 7

$$Interval\ for\ Low\ Standard = M_1 \pm 2.13 \sqrt{\frac{V_p}{6}}$$

EQ. 8

$$Interval\ for\ Target\ Standard = M_2 \pm 2.13 \sqrt{\frac{V_p}{6}}$$

EQ. 9

$$Interval\ for\ High\ Standard = M_3 \pm 2.13 \sqrt{\frac{V_p}{6}}$$

5.3.2.6.1 These intervals shall not overlap. If overlap is observed, the ability to discriminate the 10% difference in concentrations has not been demonstrated. In such a case, the standards are not acceptable.

5.3.2.6.2 In any event, the Contractor is responsible for the quality of the standards employed for analyses under this contract.

5.4 Documentation of the Verification and Preparation of Chemical Standards. It is the responsibility of each Contractor to maintain the necessary documentation to show that the chemical standards they have used in the performance of REAP analyses conform to the requirements previously listed.

5.4.1 Weighing logbooks, calculations, chromatograms, mass spectra, etc., whether produced by the Contractor or purchased from chemical supply houses, shall be maintained by the Contractor and may be subject to review during on-site laboratory evaluations. In those cases where the documentation is supportive of the analytical results of data packages sent to the Agency, such documentation is to be kept on file by the Contractor for a period of one year.

5.4.2 Upon request by the EPA, the Contractor shall submit their most recent previous year's documentation (12 months) for the verification and preparation of chemical standards within 14 days of the receipt of request to the recipients he/she designates.

5.4.3 The Agency may generate a report discussing deficiencies in the Contractor's documentation for the verification and preparation of chemical standards or may discuss the deficiencies during an on-site laboratory evaluation. In a detailed letter to the EPA, the Contractor shall address the deficiencies and the subsequent corrective action implemented by the Contractor to correct the deficiencies within 14 days of receipt of the report or the on-site laboratory evaluation. An alternate delivery schedule may be proposed by the Contractor, but it is the sole decision of the Agency to approve or disapprove the alternate delivery schedule. If an alternate delivery schedule is proposed, the Contractor shall describe in a letter to the EPA why he/she is unable to meet the delivery schedule listed in this section. The EPA will not grant an extension for greater than 14 days for the Contractor's response letter to the standards documentation report. The Contractor shall proceed and not assume that an extension will be granted until so notified by the EPA.

5.4.4 If new SOPs are required to be written or SOPs are required to be amended because of deficiencies and the subsequent corrective action implemented by the Contractor, the Contractor shall write/amend and submit the SOPs per the requirements listed in Section 4.

5.5 Corrective Actions. If the Contractor fails to adhere to the requirements listed in Section 5, the Contractor may expect, but the Agency is not limited to, the following actions: reduction of number of samples sent under the contract, suspension of sample shipment to Contractor, a GC/MS or GC tape audit, a data package audit, an on-site laboratory evaluation, a remedial laboratory evaluation sample, and/or contract sanctions, such as a Cure Notice.

6.0 REGIONAL DATA REVIEW

6.1 Contractor data are generated to meet the specific needs of EPA New England. In order to verify the usability of data for the intended purpose, the Region reviews data from the perspective of the end user, based upon functional aspects of data quality. Guidelines for data review have been developed by EPA New England. EPA New England uses these guidelines as the basis for data evaluation. The Region may augment the basic guideline review process with additional review based in site specific concerns. Regional reviews, like the sites under investigation, vary based on the nature of the problems under investigation and the appropriate response to the specific circumstances.

6.2 Regional data reviews, relating usability of the data to a specific site are part of the collective assessment process that includes review of contractual discrepancies and Contractor and method performance. These evaluations are integrated into a collective review that is necessary for Contractor administration and management and may be used to take appropriate action to correct deficiencies in the Contractor's performance.

7.0 LABORATORY EVALUATION SAMPLES

7.1 Although intralaboratory QC may demonstrate Contractor and method performance that may be tracked over time, an external performance evaluation program is an essential feature of a QA program. As a means of measuring Contractor and method performance, Contractors participate in interlaboratory comparison studies conducted by the Agency. Results from the analysis of these laboratory evaluation samples, also referred to as performance evaluation (PE) samples, will be used by the Agency to verify the Contractor's continuing ability to produce acceptable analytical data. The results are also used to assess the precision and accuracy of the analytical methods for specific analytes.

7.2 Sample sets may be provided to participating Contractors as frequently as on an SDG-by-SDG basis as a recognizable QC sample of known composition, as a recognizable QC sample of unknown composition, or not recognizable as a QC material. The laboratory evaluation samples may be sent either by the Region or the Analytical Operations Center (AOC). The results of all such quality control samples may be used as the basis for an equitable adjustment to reflect the reduced value to the Agency; may be used as the basis for rejection of data for: sample(s) within an SDG, a fraction within an SDG or the entire SDG; and/or may be used as the basis for contract action. The Contractor shall analyze the samples and return the data package and all raw data within the contract required turnaround time.

7.3 At a minimum, the results are evaluated for compound identification, quantitation, and sample contamination. Confidence intervals for the quantitation of target compounds are based on reported values using population statistics. The Agency may adjust the scores on any given laboratory evaluation sample to compensate for unanticipated difficulties with a particular sample. Normally, a fraction of the compounds spiked into the sample are not specifically listed in the contract. Contractor is required to use their most recent NIST/EPA/NIH (May 1992 release or later) and/or Wiley (1991 release or later), or equivalent, mass spectral library to tentatively identify a maximum number of non-target compounds in each fraction that are present above a minimal response. Tentative identification of these compounds, based on contractually described spectral interpretation procedures, is evaluated and integrated into the evaluation process.

7.4 A Contractor's results on the laboratory evaluation samples will determine the Contractor's performance as follows.

7.4.1 Acceptable, No Response Required (Score greater than or equal to 90%): Data meets most or all of the scoring criteria.

7.4.2 Acceptable, Response Explaining Deficiency(ies) Required (Score greater than or equal to 75% but less than 90%): Deficiencies exist in the Contractor's performance.

7.4.3 Unacceptable Performance, Response Explaining Deficiency(ies) Required (Score less than 75%): Deficiencies exist in the Contractor's performance to the extent that the EPA has determined that the Contractor has not demonstrated the capability to meet the contract requirements.

7.5 In the case of Sections 7.4.2 and 7.4.3, the Contractor shall describe the deficiency(ies) and the action(s) taken to correct the deficiency(ies) in a letter to the EPA within 14 days of receipt of notification from the Agency.

7.6 An alternate delivery schedule may be proposed by the Contractor, but it is the sole decision of the Agency to approve or disapprove the alternate delivery schedule. If an alternate delivery schedule is proposed, the Contractor shall describe in a letter to the EPA why he/she is unable to meet the delivery schedule listed in this section. The EPA will not grant an extension for greater than 14 days for the Contractor's response letter to the laboratory evaluation sample report. The Contractor shall proceed and not assume that an extension will be granted until so notified by the EPA.

7.7 If new SOPs are required to be written or SOPs are required to be amended because of the deficiencies and the subsequent corrective action implemented by the Contractor, the Contractor shall write/amend and submit the SOPs per the requirements listed in Section 4.

7.8 The Contractor shall be notified by the EPA concerning the remedy for their unacceptable performance. The Contractor may expect, but the Agency is not limited to, the following actions: reduction of the number of samples sent under the contract, suspension of sample shipment to the Contractor, a GC/MS or GC tape audit, a data package audit, an on-site laboratory evaluation, a remedial laboratory evaluation sample, and/or contract sanctions, such as a Cure Notice.

7.9 If the Contractor fails to adhere to the requirements listed in Section 7, the Contractor may expect, but the Agency is not limited to, the following actions: reduction in the number of samples sent under the contract, suspension of sample shipment to the Contractor, a GC/MS or GC tape audit, a data package audit, an on-site laboratory evaluation, a remedial laboratory evaluation sample and/or contract sanctions, such as a Cure Notice.

NOTE: The Contractor's prompt response demonstrating that corrective actions have been taken to ensure the Contractor's capability to meet contract requirements may facilitate continuation of sample scheduling.

8.0 GC/MS TAPE AUDITS

8.1 Overview. Periodically, the Agency requests the GC/MS magnetic tapes from Contractors for a specific Case in order to accomplish tape audits. Generally, tape submissions and audits are requested for the following reasons.

- Program overview,
- Indication of data quality problems from a Regional data review,
- Support for on-site audits, and
- Specific Regional requests.

8.1.1 Depending upon the reason for an audit, the tapes from a recent Case, a specific Case, or a laboratory evaluation sample may be requested. Tape audits provide a mechanism to assess adherence to contractual requirements and to ensure the consistency of the hardcopy data reported with that generated on the GC/MS tapes. This function provides external monitoring of Program QC requirements and checks adherence of the Contractor to internal QA procedures. In addition, tape audits enable the Agency to evaluate the utility, precision, and accuracy of the analytical methods.

8.1.2 The Contractor shall store all raw and processed GC/MS data on magnetic tape, in appropriate instrument manufacturer's format. This tape shall include data for samples, blanks, matrix spikes, matrix spike duplicates, initial calibrations, initial calibration verifications, continuing calibrations, and instrument performance checks (BFB and DFTPP) as well as all Contractor-generated spectral libraries and quantitation reports required to generate the data package. The Contractor shall maintain a written reference logbook of tape files of the EPA sample number, calibration data, standards, blanks, matrix spikes, and matrix spike duplicates. The logbook shall include EPA sample numbers and standard and blank IDs, identified by Case and Sample Delivery Group.

8.1.3 The Contractor is required to retain the GC/MS tapes for 365 days after submission of the reconciled Complete SDG File. When submitting GC/MS tapes to the Agency, the following materials shall be delivered in response to the request.

8.1.3.1 All associated raw data files for samples, including laboratory evaluation samples, blanks, matrix spikes, matrix spike duplicates, initial calibration standards, initial calibration verification standards, continuing calibration standards, and instrument performance check solutions (BFB and DFTPP).

8.1.3.2 All processed data files and quantitation output files associated with the raw data files described in Section 8.1.3.1.

8.1.3.3 All associated identifications and calculation files used to generate the data submitted in the data package.

8.1.3.4 All Contractor-generated mass spectral library files (NIST/EPA/NIH and/or Wiley, or equivalent, library not required).

8.1.3.5 A copy of the Contractor's written reference logbook relating tape files to EPA sample number, calibration data, standards, blanks, matrix spikes, and matrix spike duplicates. The logbook shall include EPA sample numbers and lab file identifiers for all samples, blanks, and standards, identified by Case and Sample Delivery Group.

8.1.3.6 **A directory of files on each tape.**

8.1.3.7 A copy of the completed sample data package.

8.1.3.8 A statement attesting to the completeness of the GC/MS data tape submission, signed and dated by the Contractor's laboratory manager. The Contractor shall also provide a statement attesting that the data reported have not been altered in any way. These

statements shall be part of a cover sheet that includes the following information relevant to the data tape submission:

- Contractor name,
- Date of submission,
- Case number,
- SDG number,
- GC/MS make and model number,
- Software version,
- Disk drive type (e.g., CDC, PRIAM, etc.),
- File transfer method (e.g., DSD, DTD, FTP, Aquarius, etc.), and
- Names and telephone numbers of two Contractor contacts for further information regarding the submission.

8.2 Submission of the GC/MS Tape. Upon request of the EPA, the Contractor shall send the required GC/MS tapes and all necessary documentation to the designated recipient within seven (7) days of notification. An alternate delivery schedule may be proposed by the Contractor, but it is the sole decision of the Agency to approve or disapprove the alternate delivery schedule. If an alternate delivery schedule is proposed, the Contractor shall describe in a letter to the EPA why he/she is unable to meet the delivery schedule listed in this section. The EPA will not grant an extension for greater than seven days for submission of the GC/MS tape. The Contractor shall proceed and not assume that an extension will be granted until so notified by the EPA.

NOTE: The GC/MS tapes shall be shipped according to the procedures in Exhibit F.

8.3 Responding to the GC/MS Tape Audit Report. After completion of the GC/MS tape audit, the Agency may send a copy of the GC/MS tape audit report to the Contractor or may discuss the GC/MS tape audit report at an on-site laboratory evaluation. In a detailed letter to the EPA, the Contractor shall discuss the corrective actions implemented to resolve the deficiencies listed in the GC/MS tape audit report within 14 days of receipt of the report.

8.3.1 An alternate delivery schedule may be proposed by the Contractor, but it is the sole decision of the Agency to approve or disapprove the alternate delivery schedule. If an alternate delivery schedule is proposed, the Contractor shall describe in a letter to the EPA why he/she is unable to meet the delivery schedule listed in this section. The EPA will not grant an extension for greater than 14 days for the Contractor's response letter to the GC/MS tape report. The Contractor shall proceed and not assume that an extension will be granted until so notified by the EPA.

8.3.2 If new SOPs are required to be written or SOPs are required to be amended because of the deficiencies and the subsequent corrective action implemented by the Contractor, the Contractor shall write/amend and submit the SOPs per the requirements listed in Section 4.

8.3.3 Maintenance of the Magnetic Tape Storage Device

8.3.3.1 The Contractor shall certify that the tape head alignment on the magnetic tape storage device is in compliance with the ANSI standards for nine track magnetic tapes. If the Contractor does not have documentation of alignment within the last 12 months, the Contractor must perform or have performed the manufacturer's documented head alignment procedure within 60 days of contract award. This is generally performed with a "skew" tape, certified to be in conformance with ANSI standards. The alignment must be performed by qualified personnel. The tape head alignment must be

performed at a minimum once every 12 months or when there is evidence that the tape head may be out of alignment.

8.3.3.2 The tape system, including recording head, must be in conformance with the manufacturer's physical and electrical standards. Alignment of the remaining components of the tape system such as the retracting arms, must be performed at intervals not to exceed 24 months. If the Contractor cannot demonstrate that the remaining components of the tape system are in alignment, then the Contractor must perform or have performed the manufacturer's recommended alignment procedure.

8.3.3.3 Documentation of maintenance, alignment, and repair procedures must be kept in an instrument maintenance log book for each tape device and data system. Also include any local area network components that provide a means for the transmission of data to or from the instrument data system and the tape system. Maintenance entries must include serial number, property number (if applicable), data and time of repair, name of person performing maintenance, problem description, problem resolution, date and time of failure (if applicable), and date and time placed back in service. Copies of repairs shall be kept in the maintenance documentation. Documentation of 1) data system, and 2) tape system maintenance and alignments, for the last 24 months must be made available upon written request of the EPA during a laboratory on-site evaluation. The Contractor shall always submit a GC/MS tape from a tape system in conformance with the manufacturer's physical and electrical standards and alignment according to manufacturer's procedures.

8.4 Corrective Actions. If the Contractor fails to adhere to the requirements listed in Section 8, the Contractor may expect, but the Agency is not limited to, the following actions: reduction in the number of samples sent under the contract, suspension of sample shipment to the Contractor, an on-site laboratory evaluation, a GC/MS tape audit, a data package audit, a remedial laboratory evaluation sample, and/or contract sanctions, such as a Cure Notice.

9.0 GC TAPE AUDITS

9.1 Overview. Periodically, the Agency requests the GC magnetic tapes from Contractors for a specific Case in order to accomplish tape audits. Generally, tape submissions and audits are requested for the following reasons.

- Program overview,
- Indication of data quality problems from a Regional data review,
- Support for on-site audits, and
- Specific Regional requests.

9.1.1 Depending upon the reason for an audit, the tapes from a recent Case, a specific Case, or a laboratory evaluation sample may be requested. Tape audits provide a mechanism to assess adherence to contractual requirements and to ensure the consistency of the hardcopy data reported with that generated on the GC tapes. This function provides external monitoring of Program QC requirements and checks adherence of the Contractor to internal QA procedures. In addition, tape audits enable the Agency to evaluate the utility, precision, and accuracy of the analytical methods.

9.1.2 The Contractor shall store all raw and processed GC data on magnetic tape, in appropriate instrument manufacturer's format. This tape shall include data from both the primary and confirmatory columns for samples, blanks, matrix spikes, matrix spike duplicates, initial calibrations, initial calibration verifications, and continuing calibrations required to generate the data package. The Contractor shall also submit any GC/MS tapes (Section 8) related to any samples and blanks analyzed as part of GC/MS confirmation The Contractor shall maintain a written reference logbook of tape files of the EPA sample number, calibration data, standards, blanks, matrix spikes, and matrix spike duplicates. The logbook shall include EPA sample numbers and standard and blank IDs, identified by Case and Sample Delivery Group.

9.1.3 The Contractor is required to retain the GC tapes for 365 days after submission of the reconciled Complete SDG File. When submitting GC tapes to the Agency, the following materials shall be delivered in response to the request.

9.1.3.1 All associated raw data files for samples, including laboratory evaluation samples, blanks, matrix spikes, matrix spike duplicates, initial calibration standards, initial calibration verification standards, and continuing calibration standards.

9.1.3.2 All processed data files and quantitation output files associated with the raw data files described in Section 9.1.3.1.

9.1.3.3 All associated identifications and calculation files used to generate the data submitted in the data package.

9.1.3.4 All GC/MS confirmation data (as specified in Section 8), including Contractor-generated mass spectral library files (NIST/EPA/NIH and/or Wiley, or equivalent, library not required).

9.1.3.5 A copy of the Contractor's written reference logbook relating tape files to EPA sample number, calibration data, standards, blanks, matrix spikes, and matrix spike duplicates. The logbook shall include EPA sample numbers and lab file identifiers for all samples, blanks, and standards, identified by Case and Sample Delivery Group.

9.1.3.6 **A directory of files on each tape.**

9.1.3.7 A copy of the completed sample data package.

9.1.3.8 A statement attesting to the completeness of the GC data tape submission, signed and dated by the Contractor's laboratory manager. The Contractor shall also provide a statement attesting

that the data reported have not been altered in any way. These statements shall be part of a cover sheet that includes the following information relevant to the data tape submission:

- Contractor name,
- Date of submission,
- Case number,
- SDG number,
- GC make and model number,
- Type of GC detector,
- Software version,
- Disk drive type (e.g., CDC, PRIAM, etc.),
- File transfer method (e.g., DSD, DTD, FTP, Aquarius, etc.), and
- Names and telephone numbers of two Contractor contacts for further information regarding the submission.

9.2 Submission of the GC Tape. Upon request of the EPA, the Contractor shall send the required GC tapes and all necessary documentation to the designated recipient within seven (7) days of notification. An alternate delivery schedule may be proposed by the Contractor, but it is the sole decision of the Agency to approve or disapprove the alternate delivery schedule. If an alternate delivery schedule is proposed, the Contractor shall describe in a letter to the EPA why he/she is unable to meet the delivery schedule listed in this section. The EPA will not grant an extension for greater than seven days for submission of the GC tape. The Contractor shall proceed and not assume that an extension will be granted until so notified by the EPA.

NOTE: The GC tapes shall be shipped according to the procedures in Exhibit F.

9.3 Responding to the GC Tape Audit Report. After completion of the GC tape audit, the Agency may send a copy of the GC tape audit report to the Contractor or may discuss the GC tape audit report at an on-site laboratory evaluation. In a detailed letter to the EPA, the Contractor shall discuss the corrective actions implemented to resolve the deficiencies listed in the GC tape audit report within 14 days of receipt of the report.

9.3.1 An alternate delivery schedule may be proposed by the Contractor, but it is the sole decision of the Agency to approve or disapprove the alternate delivery schedule. If an alternate delivery schedule is proposed, the Contractor shall describe in a letter to the EPA why he/she is unable to meet the delivery schedule listed in this section. The EPA will not grant an extension for greater than 14 days for the Contractor's response letter to the GC tape report. The Contractor shall proceed and not assume that an extension will be granted until so notified by the EPA.

9.3.2 If new SOPs are required to be written or SOPs are required to be amended because of the deficiencies and the subsequent corrective action implemented by the Contractor, the Contractor shall write/amend and submit the SOPs per the requirements listed in Section 4.

9.3.3 Maintenance of the Magnetic Tape Storage Device

Refer to Section 8.3.3 for required maintenance.

9.4 Corrective Actions. If the Contractor fails to adhere to the requirements listed in Section 9, the Contractor may expect, but the Agency is not limited to, the following actions: reduction in the number of samples sent under the contract, suspension of sample shipment

to the Contractor, an on-site laboratory evaluation, a GC and/or GC/MS tape audit, a data package audit, a remedial laboratory evaluation sample, and/or contract sanctions, such as a Cure Notice.

10.0 DATA PACKAGE AUDITS

10.1 Overview. Data package audits are performed by the Agency for program overview and specific concerns to assess the technical quality of the data and evaluate overall Contractor performance. They provide the Agency with an in-depth inspection and evaluation of the Case data package with regard to achieving QA/QC acceptability. Data packages are periodically selected from recently received Cases. They are evaluated for the technical quality of hardcopy raw data, quality assurance, and adherence to contractual requirements. A thorough review of the raw data is completed, including: a check of instrument printouts, quantitation reports, chromatograms, spectra, library searches and other documentation for deviations from the contractual requirements, a check for transcription and calculation errors, a review of the qualifications of the Contractor personnel involved with the Case, and a review of all current SOPs on file. Standardized procedures have been established to assure uniformity of the auditing process.

10.2 Responding to the Data Package Audit Report. After completing the data package audit, the Agency may send a copy of the data package audit report to the Contractor or may discuss the data package audit report at an on-site laboratory evaluation. In a detailed letter to the EPA, the Contractor shall discuss the corrective actions implemented to resolve the deficiencies listed in the data package audit report within 14 days of receipt of the report.

10.2.1 An alternate delivery schedule may be proposed by the Contractor, but it is the sole decision of the Agency to approve or disapprove the alternate delivery schedule. If an alternate delivery schedule is proposed, the Contractor shall describe in a letter to the EPA why he/she is unable to meet the delivery schedule listed in this section. The EPA will not grant an extension for greater than 14 days for the Contractor's response letter to the data package report. The Contractor shall proceed and not assume that an extension will be granted until so notified by the EPA.

10.2.2 If new SOPs are required to be written or SOPs are required to be amended because of the deficiencies and the subsequent corrective action implemented by the Contractor, the Contractor shall write/amend and submit the SOPs per the requirements listed in Section 4.

10.3 Corrective Actions. If the Contractor fails to adhere to the requirements listed in Section 10, the Contractor may expect, but the Agency is not limited to, the following actions: reduction in the numbers of samples sent under the contract, suspension of sample shipment to the Contractor, an on-site laboratory evaluation, a GC/MS or GC tape audit, a data package audit, a remedial laboratory evaluation sample, and/or contract sanctions, such as a Cure Notice.

11.0 ON-SITE LABORATORY EVALUATIONS

11.1 Overview. At a frequency dictated by a Contractor's performance, the EPA will conduct an on-site laboratory evaluation. On-site laboratory evaluations are carried out to monitor the Contractor's ability to meet selected terms and conditions specified in the contract. The evaluation process incorporates two separate categories: a quality assurance evaluation and an evidentiary audit.

11.2 Quality Assurance On-Site Evaluation. Quality assurance evaluators inspect the Contractor's facilities to verify the adequacy and maintenance of instrumentation, the continuity of personnel meeting experience or education requirements, and the acceptable performance of analytical and QC procedures.

11.2.1 The Contractor shall expect that items to be monitored will include, but not be limited to, the following items:

- Size and appearance of the facility,
- Quantity, age, availability, scheduled maintenance and performance of instrumentation,
- Availability, appropriateness, and utilization of the LQAP and SOPs,
- Staff qualifications and experience, and personnel training programs,
- Reagents, standards, and sample storage facilities,
- Standard preparation logbooks and raw data,
- Bench sheets and analytical logbook maintenance and review, and
- Review of the Contractor's sample analysis/data package inspection/data management procedures.

11.2.2 Prior to an on-site evaluation, various documentation pertaining to performance of the specific Contractor is integrated in a profile package for discussion during the evaluation. Items that may be included are previous on-site reports, laboratory evaluation sample scores, Regional review of data, Regional QA materials, GC/MS or GC tape audit reports, data audit reports, and date trend reports.

11.3 Evidentiary Audit. Evidence auditors conduct an on-site laboratory evaluation to determine if Contractor policies and procedures are in place to satisfy evidence handling requirements as stated in Exhibit F. The evidence audit comprises a procedural audit, an audit of written SOPs, and an audit of analytical project file documentation.

11.3.1 Procedural Audit. The procedural audit consists of review and examination of actual standard operating procedures and accompanying documentation for the following Contractor operations: sample receiving, sample storage, sample identification, sample security, sample tracking (from receipt to completion of analysis) and analytical project file organization and assembly.

11.3.2 Written SOPs Audit. The written SOPs audit consists of review and examination of the written SOPs to determine if they are accurate and complete for the following Contractor operations: sample receiving, sample storage, sample identification, sample security, sample tracking (from receipt to completion of analysis) and analytical project file organization and assembly.

11.3.3 Analytical Project File Evidence Audit. The analytical project file evidence audit consists of review and examination of the analytical project file documentation. The auditors review the files to determine:

- The accuracy of the document inventory,
- The completeness of the file,

- The adequacy and accuracy of the document numbering system,
- Traceability of sample activity,
- Identification of activity recorded on the documents, and
- Error correction methods.

11.4 Discussion of the On-Site Team's Findings. During the debriefing, the auditors present their findings and recommendations for corrective actions necessary to the Contractor personnel.

11.5 Corrective Action Reports for Follow-Through to Quality Assurance and Evidentiary Audit Reports. Following an on-site laboratory evaluation, quality assurance and/or evidentiary audit reports which discuss deficiencies found during the on-site evaluation may be sent to the Contractor. In a detailed letter, the Contractor shall discuss the corrective actions implemented to resolve the deficiencies discussed during the on-site evaluation and discussed in the report(s) to the EPA within 14 days of receipt of the report.

11.5.1 An alternate delivery schedule may be proposed by the Contractor, but it is the sole decision of the Agency to approve or disapprove the alternate delivery schedule. If an alternate delivery schedule is proposed, the Contractor shall describe in a letter to the EPA why he/she is unable to meet the delivery schedule listed in this section. The EPA will not grant an extension for greater than 14 days for the Contractor's response letter to the quality assurance and evidentiary audit report. The Contractor shall proceed and not assume that an extension will be granted until so notified by the EPA.

11.5.2 If new SOPs are required to be written or SOPs are required to be amended because of the deficiencies and the subsequent corrective action implemented by the Contractor, the Contractor shall write/amend and submit the SOPs per the requirements listed in Section 4.

11.6 Corrective Actions. If the Contractor fails to adhere to the requirements listed in Section 11, the Contractor may expect, but the Agency is not limited to, the following actions: reduction in the number of samples sent under the contract, suspension of sample shipment to the Contractor, an on-site laboratory evaluation, a GC/MS or GC tape audit, a data package audit, a remedial laboratory evaluation sample, and/or contract sanctions, such as a Cure Notice.

12.0 QUALITY ASSURANCE AND DATA TREND ANALYSIS

12.1 Data submitted by Contractors are subject to review from several aspects: compliance with contract-required QC, usability, and full data package evaluation. Problems resulting from any of these reviews may determine the need for a GC/MS or GC tape audit, an on-site laboratory evaluation and/or a remedial laboratory evaluation sample. In addition, QC prescribed in the methods provides information that is continually used by the Agency to assess sample data quality, Contractor data quality and Regional data quality via data trend analysis. Trend analysis is accomplished by entering data into a computerized database. Statistical reports that evaluate specific anomalies or disclose trends in many areas, including the following, are generated from this database:

- Surrogate spike recovery,
- Laboratory evaluation sample results,
- Blanks,
- GC/MS instrument performance checks (BFB and DFTPP),
- Initial calibration, initial calibration verification, and continuing calibration data, and
- Other QC and method parameters.

12.2 Region-wide statistical results are used to rank Contractors in order to observe the relative performance of each Contractor using a given protocol against its peers. The reports are also used to identify trends within Contractors. The results of many of these trend analyses are included in the overall evaluation of a Contractor's performance, and are reviewed to determine if corrective action or an on-site laboratory evaluation may be required to ensure that the Contractor can meet the QA/QC requirements of the contract. Contractor performance over time is monitored using these trend analysis techniques to detect departures of Contractor output from required or desired levels of quality control, and to provide an early warning of Contractor QA/QC problems which may not be apparent from the results of an individual Case.

12.3 As a further benefit to the Region, the database provides the information needed to establish performance-based criteria in updated analytical protocols, where advisory criteria have been previously used. The vast empirical data set produced by Contractors is carefully analyzed, with the results augmenting theoretical and research-based performance criteria. The result is a continuously monitored set of quality control and performance criteria specifications of what is routinely achievable and expected of environmental chemistry Contractors engaged in mass production analysis of environmental samples. This, in turn, assists the Agency in meeting its objectives of obtaining data of known and documented quality.

13.0 DATA MANAGEMENT

13.1 Data management procedures are defined as procedures specifying the acquisition or entry, update, correction, deletion, storage and security of computer-readable data and files. These procedures shall be in written form and contain a clear definition for all databases and files used to generate or resubmit deliverables. Key areas of concern include system organization (including personnel and security), documentation operations, traceability and quality control.

13.2 Data manually entered from hardcopy shall be subject to quality control and the error rates estimated. Systems shall prevent entry of incorrect or out-of-range data and alert data entry personnel of errors. In addition, data entry error rates shall be estimated and recorded on a monthly basis by reentering a statistical sample of the data entered and calculating discrepancy rates by data element.

13.3 The record of changes in the form of corrections and updates to data originally generated, submitted, and/or resubmitted shall be documented to allow traceability of updates. Documentation shall include the following for each change.

- Justification or rationale for the change.
- Initials of the person making the change(s). Data changes shall be implemented and reviewed by a person or group independent of the source generating the deliverable.
- Documentation of changes shall be retained according to the schedule of the original deliverable.
- Resubmitted deliverables shall be reinspected as a part of the Contractor's internal inspection process prior to resubmission. The entire deliverable, not just the changes, shall be inspected.
- The Contractor's laboratory manager shall approve changes to originally submitted deliverables.
- Documentation of data changes may be requested by Contractor auditors.

13.4 Life cycle management procedures shall be applied to computer software systems developed by the Contractor to be used to generate and edit contract deliverables. Such systems shall be thoroughly tested and documented prior to utilization.

13.4.1 A software test and acceptance plan including test requirements, test results and acceptance criteria shall be developed, followed, and available in written form.

13.4.2 System changes shall not be made directly to production systems generating deliverables. Changes shall be made first to a development system and tested prior to implementation.

13.4.3 Each version of the production system will be given an identification number, date of installation, date of last operation and archived.

13.4.4 System and operations documentation shall be developed and maintained for each system. Documentation shall include a user's manual and an operations and maintenance manual.

13.4.5 This documentation shall be available for on-site review and/or upon written request by the EPA.

13.5 Individual(s) responsible for the following functions shall be identified.

- System operation and maintenance, including documentation and training,
- Database integrity, including data entry, data updating and quality control, and

- Data and system security, backup and archiving.